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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,222	12/01/2003	Jon Elliot Adler	54072D1	3212

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HUNTON & WILLIAMS LLP
INTELLECTUAL PROPERTY DEPARTMENT
1900 K STREET, N.W.
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WASHINGTON, DC 20006-1109

EXAMINER

BRANNOCK, MICHAEL T

ART UNIT	PAPER NUMBER
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1649

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/724,222	Applicant(s) ADLER ET AL.	
	Examiner Michael Brannock	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 272-308 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 272-308 is/are objected to.
- 8) ☒ Claim(s) 272-308 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application: Claims and Amendments

Applicant is notified that the amendments put forth on 1/11/2007, have been entered in full.

Claims 1-271 have been canceled. New claims 272-308 are currently under examination.

Response to Amendment

Applicant is notified that any outstanding objection or rejection that is not expressly maintained in this Office action has been withdrawn in view of Applicant's amendments and upon further consideration of the word "putatively" as it is used in the claims, i.e. see page 2 of the prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 272-308 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the following reasons.

Claim 272 requires a polypeptide having the amino acid sequence "encoded by SEQ ID NO: 17"; as SEQ ID NO: 17 is an amino acid sequence it is unclear what limitations the word encoded places on the claim. It suggested that the claim be reworded to read "polypeptide having the amino acid sequence of SEQ ID NO: 17.

Similarly, claims 272-279 require a polypeptide “contained in” SEQ ID NO: 17 it is unclear what limitations the phrase “contained in” places on the claim. It is suggested that the claim read “polypeptide of SEQ ID NO: 17”.

Claim 285 requires that the polypeptide is expressed by a cell. As polypeptide can be expressed by a cell and then purified or, alternatively, expressed by the cell and used without purification, it is unclear what the claim is intended to encompass.

Claim 286 requires the polypeptide to be comprised on a membrane. It is unclear what this means, and it is suggested that the claimed be amended to indicate if the polypeptide is expressed in the cell membrane or attached to it.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 272-308 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the following reasons.

The claims are directed to methods for identifying a compound that putatively modulates or elicits taste in a human subject, specifically with regard to a polypeptide of SEQ ID NO: 17 which is termed hT1R1. The specification asserts it is believed that T1R protein family members are components of the taste transduction pathway and may be involved in taste detection of sweet substances and/or other taste modalities and particularly that T1R1 and T1R2 may

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physically interact or, alternatively, that they may act independently, see page 9. It is generally agreed in the art that only T1R3 is capable of acting a taste receptor alone, see page 192, col 1, of Temussi-P et al., J. Mol. Recognition 19(188-199)2006. Thus, the claims are not directed to a functional taste receptor. Additionally, the claims require that the identified compound modulate the specific binding of another compound that specifically binds to the polypeptide of SEQ ID NO: 17, yet no such compounds have been taught in the specification. As set forth previously, Hoon *et al.*, *Cell* 96(541-551)1999, report that “We have attempted to determine the ligand/tastant specificity of TR1 and TR2 using a variety of strategies but have been hampered by the difficulty of functionally expressing these molecules in heterologous system see col 1 of page 547”. The art regarding T1R receptors, as exemplified by Hoon et al., recognizes the complexity, unpredictability, and non-routine nature of the work involved in trying to assay functional T1R receptors and their ligands. The specification has not taught what compounds are to be used in the claimed method.

Although Applicant does not appear to address this issue with regard to enablement for compounds that specifically binds to T1R1 and putatively modulate taste, Applicant argues, essentially, at pages 9-10 of the 1/11/2007 that one skilled in the art could find such ligands. This argument has been fully considered but not deemed persuasive, for the reasons provided above.

Claims 235-270 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

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art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As set forth above, the claims require embodiments wherein the identified compound modulate the specific binding of another compound that specifically binds to the polypeptide of SEQ ID NO: 17, yet no such specific binding compounds have been taught in the specification. The specification has not taught where to obtain such and it does not assert that any particular compound would have this property. Thus the one skilled in art would not recognize that Applicant was in possession of such compounds that are needed to practice the claimed methods. Applicant argues, essentially, at pages 9-10 of the 1/11/2007 that one skilled in the art could find such ligands, e.g. by using artificial and natural sweet and savory compounds. This argument has been fully considered but not deemed persuasive; the specification does not teach what type of compounds bind to T1R1.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

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with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 272-308 are provisionally rejected on the ground of nonstatutory double patenting over claims 235-286 of copending Application No. 10/724223. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the instant claims are directed to binding assays whereas those of copending Application No. 10/724223 recite "functional assays", however functional assays of this type are assays of binding, thus the instant claims would be covered by any patent granted in the 10/724223 application.

As per Applicant's request, this provisional rejection will be held in abeyance.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867. Official papers filed by fax should be directed to **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB



April 15, 2007



JANET L. ANDRES
SUPERVISORY PATENT EXAMINER